

Product Update:

fosfomycin trometamol granules for oral solution (equivalent to 3g fosfomycin)
(Monuril®) SMC No. (1163/16)

Profile Pharma Ltd

10 June 2016 (*Issued 5 August 2016*)

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

fosfomycin trometamol (Monuril®) is accepted for use within NHS Scotland.

Indication under review:

- Treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females.
- Prophylaxis in diagnostic and surgical transurethral procedures.

Consideration should be given to national guidance on the appropriate use of antibacterial agents.

Unlicensed preparations of oral fosfomycin have been used in the NHS in Scotland. The availability of fosfomycin trometamol (Monuril®) provides a licensed preparation. Estimated patient numbers are expected to be small.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 06 April 2016.

**Chairman,
Scottish Medicines Consortium**

Published 12 September 2016